

104TH CONGRESS
2D SESSION

H. R. 3959

To establish a demonstration project to study and provide coverage of routine patient care costs for Medicare beneficiaries with cancer who are enrolled in an approved clinical trial program.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 1996

Mrs. JOHNSON of Connecticut introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To establish a demonstration project to study and provide coverage of routine patient care costs for Medicare beneficiaries with cancer who are enrolled in an approved clinical trial program.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Cancer Clini-
5 cal Trial Program Coverage Act of 1996”.

1 **SEC. 2. MEDICARE CANCER PATIENT DEMONSTRATION**
2 **PROJECT.**

3 (a) ESTABLISHMENT.—Not later than January 1,
4 1997, the Secretary of Health and Human Services (in
5 this Act referred to as the “Secretary”) shall establish a
6 demonstration project which provides for payment under
7 the Medicare Program under title XVIII of the Social Se-
8 curity Act (42 U.S.C. 1395 et seq.) of routine patient care
9 costs—

10 (1) which are provided to an individual diag-
11 nosed with cancer and enrolled in the Medicare Pro-
12 gram under such title as part of the individual’s par-
13 ticipating in an approved clinical trial program; and
14 (2) which are not otherwise eligible for payment
15 under such title for individuals who are entitled to
16 benefits under such title.

17 (b) APPLICATION.—The beneficiary cost sharing pro-
18 visions under the Medicare Program, such as deductibles,
19 coinsurance, and copayment amounts, shall apply to any
20 individual participating in a demonstration project con-
21 ducted under this Act.

22 (c) APPROVED CLINICAL TRIAL PROGRAM.—For
23 purposes of this Act, the term “approved clinical trial pro-
24 gram” means a clinical trial program which is approved
25 by—

26 (1) the National Institutes of Health;

1 (2) a National Institutes of Health cooperative
2 group or a National Institutes of Health center;

3 (3) the Food and Drug Administration (in the
4 form of an investigational new drug or device exemp-
5 tion);

6 (4) the Department of Veterans Affairs;

7 (5) the Department of Defense; or

8 (6) a qualified nongovernmental research entity
9 identified in the guidelines issued by the National
10 Institutes of Health for center support grants.

11 (d) ROUTINE PATIENT CARE COSTS.—

12 (1) IN GENERAL.—For purposes of this Act,
13 “routine patient care costs” shall include the costs
14 associated with the provision of items and services
15 that—

16 (A) would otherwise be covered under the
17 Medicare Program if such items and services
18 were not provided in connection with an ap-
19 proved clinical trial program; and

20 (B) are furnished according to the design
21 of an approved clinical trial program.

22 (2) EXCLUSION.—For purposes of this Act,
23 “routine patient care costs” shall not include the
24 costs associated with the provision of—

1 (A) an investigational drug or device, un-
2 less the Secretary has authorized the manufac-
3 turer of such drug or device to charge for such
4 drug or device; or

5 (B) any item or service supplied without
6 charge by the sponsor of the approved clinical
7 trial program.

8 **SEC. 3. STUDY, REPORT, AND TERMINATION.**

9 (A) STUDY.—The Secretary shall study the impact
10 on the Medicare Program under title XVIII of the Social
11 Security Act of covering routine patient care costs of indi-
12 viduals with a diagnosis of cancer and other diagnoses,
13 who are entitled to benefits under such title and who are
14 enrolled in an approved clinical trial program.

15 (b) REPORT TO CONGRESS.—Not later than January
16 1, 2001, the Secretary shall submit a report to Congress
17 that contains a statement regarding—

18 (1) any incremental cost to the Medicare Pro-
19 gram under title XVIII of the Social Security Act
20 resulting from the provisions of this Act; and

21 (2) a projection of expenditures under the Med-
22 icare Program if coverage of routine patient care
23 costs in an approved clinical trial program were ex-
24 tended to individuals entitled to benefits under the

1 Medicare Program who have a diagnosis other than
2 cancer.

3 (c) TERMINATION.—The provisions of this Act shall
4 not apply after June 30, 2001.

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